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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,538	10/31/2005	Yongzhi Xi	272331US0PCT	7166

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EXAMINER	
LONG, SCOTT	

ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
09/17/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/534,538	XI ET AL.	
	Examiner	Art Unit	
	SCOTT LONG	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/28/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner acknowledges receipt of Applicant's Remarks and Affidavit, filed on 29 June 2009.

Claim Status

Claims 1-11 and 20-21 are canceled. None of the remaining claims were amended. Claims 12-19 are under current examination.

Priority

This application claims benefit as a 371 of PCT/CN03/00967 (filed 11/14/2003). This application claims benefit from foreign patent application (CHINA) 02149375.8 (filed 11/14/2002). The instant application has been granted the benefit date, 14 November 2003, from the application PCT/CN03/00967.

Information Disclosure Statement

This Information Disclosure Statements (IDS) filed on 7/28/2009, consisting of 1 sheet is in compliance with 37 CFR 1.97. Accordingly, the examiner has considered the Information Disclosure Statements.

37 CFR 1.132 Declaration

The examiner acknowledges receipt of the Declaration under 37 CFR 1.132 by Dr. Yongzhi Xi filed on 29 June 2009.

The Declaration under 37 CFR 1.132 filed 29 June 2009 is insufficient to overcome the rejection of claims 12-19 based upon obviousness over Upholt et al. (PNAS. April 1986; Vol.83: 2325-2329) in view of Xi et al. (accession number AAK98621, direct submission on 19 July 2001) and further in view of Matsumoto et al (US-6,010,722, issued 4 January 2000) as set forth in the last Office action because:

The affiant has sworn that the chicken collage II cDNA sequence provided on 19 July 2001 (Genbank accession number AY046949) is different from the corrected chicken collage II cDNA sequence provided in 2003 and 2006.

The affiant has failed to show that the Xi et al. chicken collagen II polypeptide sequences identified in Genbank accession number AAK98621 are different from those provided by direct submission on 19 July 2001.

The afffiant's submission was an attempt to invalidate Xi et al. (Genbank accession number AAK98621) as prior art. The affiant's statements are sufficient to indicate that the nucleic acid sequences submitted on 19 July 2001 are inaccurate. However, the affiant's statements are not sufficient to indicate that the polypeptide sequences submitted on 19 July 2001 are inaccurate. The Affidavit does not explicitly state that the polypeptide sequences submitted on 19 July 2001 are different from those submitted later. Without such a statement, the examiner concludes that the polypeptide sequence for Chicken Collagen II submitted in 2001 is the same that submitted at a

later date. If the applicant makes clear that the polypeptide sequence for Chicken Collagen II submitted in 2001 is the different from the polypeptide sequence submitted in 2003 or 2006, the examiner would consider this sufficient to overcome the pending obviousness rejection.

The obviousness rejection was based upon the chicken collagen II protein sequence provided by Xi et al. (Genbank accession number AAK98621) as a direct submission on 19 July 2001. See rejection below, especially *Ex parte Kubin* reasoning.

The examiner finds that the facts submitted by the affiant do not overcome the rejection of claims 12-19 as obviousness over Upholt in view of Xi and further in view of Matsumoto because the Xi et al. (Genbank accession number AAK98621) provided as a direct submission on 19 July 2001 provided an accurate amino acid sequence for chicken collagen II.

Upon consideration of the facts taught by the prior art and the information submitted by the Affiant, the balance of evidence indicates that the prior art teaches an accurate amino acid sequence for chicken collagen II, which can be used to support the pending obviousness rejection. Therefore, the rejection of claims 12-19 based upon obviousness over Upholt et al. (PNAS. April 1986; Vol.83: 2325-2329) in view of Xi et al. (accession number AAK98621, direct submission on 19 July 2001) and further in view of Matsumoto et al (US-6,010,722, issued 4 January 2000) is not overcome by the 37 CFR 1.132 Declaration submitted by Dr. Yongzhi Xi.

RESPONSE TO ARGUMENTS

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-19 remain rejected under 35 U.S.C. 103(a) as being obvious over unpatentable over Upholt et al. (PNAS. April 1986; Vol.83: 2325-2329) in view of Xi et

al. (accession number AAK98621, direct submission on 19 July 2001) and further in view of Matsumoto et al (US-6,010,722, issued 4 January 2000) for the reasons of record and the comments below.

The applicant's arguments have been fully considered but are unpersuasive.

The applicant makes two specific arguments in traverse of the obviousness rejection: (1) Xi et al. (accession number AAK98621, direct submission on 19 July 2001) is not proper prior art and (2) the references do not provide the requisite reasonable predictability of success.

The examiner has addressed the propriety of Xi et al. as prior art in the evaluation of the 37 CFR 1.132 Declaration submitted by Dr. Yongzhi Xi. In summary, the examiner found that the 37 CFR 1.132 Declaration submitted by Dr. Yongzhi Xi failed to indicate that the amino acid sequence for chicken collagen II was inaccurate. Therefore, the examiner assumes that the accurate amino acid sequence for chicken collagen II was available, even if only for a week after being submitted on 19 July 2001, and available as prior art only when used for its disclosure of the accurate amino acid sequence for chicken collagen II. Accordingly, the examiner finds the applicant's argument unpersuasive.

Regarding the argument that “the references do not provide the requisite reasonable predictability of success,” the examiner disagrees with the applicant's view regarding predictability of success. The applicant suggests that the complexity of the chicken collage II gene makes the sequencing of chicken collagen II “not so routine” and that a skilled artisan would not have reasonably expected success in sequencing

the chicken type II collagen cDNA. In particular, the applicant points to the comments by Upholt, in which they had difficulty in obtaining the 5' end of chicken collagen type II cDNA. The applicant has provided a reference (Nah et al. Journal of Biological Chemistry. 5 Dec 1991; 266(34): 23446-23452) in the IDS, submitted 7/28/2009, which demonstrates that the Upholt group later obtained the entire cDNA of chicken collagen type II, including the 5' region which was difficult to obtain in the April 1986 PNAS reference. Therefore, the examiner concludes that a skilled artisan would have expected success in obtaining the sequence of the entire cDNA of chicken collagen type II. Therefore, the examiner finds the applicant's argument unpersuasive.

In addition, MPEP 2143 indicates (in *Ex parte Kubin*, 83 USPQ2d 1410 (Bd. Pat. App. & Int. 2007)) that a claimed polynucleotide sequence would be obvious over a polypeptide sequence disclosed by the prior art, if the function of the protein was known and it was routine for a person of ordinary skill in the art to obtain its corresponding polynucleotide sequence.

Therefore, the examiner hereby maintains the rejection of claims 12-19 under 35 U.S.C. 103(a) as being obvious over Upholt et al in view of Xi et al. and further in view of Matsumoto et al.

The examiner reiterates the pending rejection:

Claims 12-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Upholt et al. (PNAS. April 1986; Vol.83: 2325-2329) in view of Xi et al. (accession number AAK98621, direct submission on 19 July 2001) and further in view of Matsumoto et al (US-6,010,722, issued 4 January 2000).

Claim 12 is directed to an isolated polynucleotide of SEQ ID NO:1. The specification describes SEQ ID NO:1 as genomic DNA encoding chicken collagen II (page 26 and 10). Upholt et al. teach genomic DNA chicken α1 (II) procollagen gene.

Claim 13 is directed to an isolated polynucleotide of SEQ ID NO:2. The specification describes SEQ ID NO:2 as chicken collagen II cDNA. Upholt et al. describe sequencing of the mRNA encoding regions of chicken collagen α1 (II) (page 2325). However, Upholt et al. does not explicitly provide the sequence as the claimed SEQ ID NO:2. However, a polypeptide sequence submitted by Xi et al. in 2001 is 100% identical to SEQ ID NO:3 of the instant application. The Specification indicates that SEQ ID NO:3 is the polypeptide sequence for full length chicken type II collagen. Accordingly, the chicken collagen II cDNA sequence of the instant application would be obvious as suggested by *Ex parte Kubin*, 83 USPQ2d 1410 (Bd. Pat. App. & Int. 2007).

Claims 14-19 are directed to vectors and cells comprising the chicken collagen II genes of claims 12-13, recombinant proteins generated therefrom, method of producing recombinant chicken collagen II, compositions of recombinant chicken collagen II, food additives comprising recombinant chicken collagen II.

Upholt et al. teach genomic DNA chicken α1 (II) procollagen gene. Upholt et al. describe sequencing of the mRNA encoding regions of chicken collagen α1 (II) (page 2325). BLAST results showing minor differences between the GenBank sequence submitted by Upholt in 1986 and the sequence submitted by the applicant in PCT/CN03/00967 (filed 11/14/2003). The examiner acknowledges that there are minor differences between the two sequences, particularly where repetitive stretches of A's or

T's predominate. In addition, Upholt describe in their Materials and Methods section (page 2325, col.2) that both strands were not sequenced and that only 99% of the mRNA encoding sequence was sequenced. Because Upholt has clearly identified their nucleic acid as chicken type II procollagen gene and while not identical, it is almost identical to the claimed genomic and cDNA sequences, and given the advances in sequencing during the intervening 17 years, the examiner concludes the sequences of Upholt are suggest the claimed sequences. The sequences claimed by the applicant are not different alleles of chicken type II collagen, rather they are only more accurate versions of sequences first identified by Upholt.

The sequence submitted by Xi et al. in 2001 is 100% identical to SEQ ID NO:3 of the instant application. The Specification indicates that SEQ ID NO:3 is the polypeptide sequence for full length chicken type II collagen.

The nucleic acids disclosed by Upholt et al. taken with the polypeptide sequence of Xi et al. are obvious over the chicken type II collagen cDNA. Together this information makes obvious any critical feature of the genomic sequence not satisfied by the chicken α1 (II) procollagen genomic DNA sequence not perfectly matching the instantly claimed genomic sequence.

Matsumoto et al. teach, “oral drugs and functional foods [which] contain type-II collagen” (abstract). Matsumoto et al. teach that the type II collagen can be chicken collagen (col.3, line 40). Matsumoto et al. teach that the type-II collagen can be made using “recombinant DNA technology” (col.3, lines 46-47). Intrinsically, to use recombinant DNA technology for producing type-II chicken collagen, a skilled artisan

would need to have cells comprising vectors comprising isolated nucleic acids encoding chicken collagen II. To the extent to which the pharmaceutical composition comprising CCII might have an enabled use (e.g. – a food additive), Matsumoto et al. suggest the limitations of claims 14-19.

It would have been obvious to the person of ordinary skill in the art at the time of the invention was made to utilize the sequences of Upholt et al. in view of Xi et al. to express recombinant forms of chicken collagen II for use in the pharmaceutical compositions of Matsumoto et al.

Regarding the rationale for simple substitution of one known, equivalent element for another to obtain predictable results, the claim(s) would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Each of the elements (specific chicken collagen II sequences and methods of recombinant protein production of chicken collagen II and uses therefor) is taught by Upholt et al. or Xi et al. or Matsumoto et al. It would be therefore predictably obvious to substitute a known element (chicken collagen II nucleic acid) in recombinant production of chicken collagen II for food additives.

Therefore the products and methods as taught by Upholt et al. in view of Xi et al. and further in view of Matsumoto et al. would have been *prima facie* obvious over the products and methods of the instant application.

Conclusion

THIS ACTION IS MADE FINAL. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims are allowed.

Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SDL/ Scott Long
Patent Examiner, Art Unit 1633

/Q. JANICE LI, M.D./
Primary Examiner, Art Unit 1633